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June 2, 2021

VIA ECF

Honorable Robert Kugler, U.S.D.J.
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 4D
4th and Cooper Streets
Camden, New Jersey 08101

Honorable Thomas I. Vanaskie (Ret.)
Special Master
Stevens & Lee
1500 Market St., East Tower, Suite 1800
Philadelphia, Pennsylvania 19103-7360

Re: ***In re Valsartan, Losartan, and Irbesartan Liability Litigation*, Case No. 1:19-md-02875-RBK (D.N.J.)**

Dear Judge Kugler and Judge Vanaskie:

Please accept this letter on behalf of Plaintiffs in advance of the June 3, 2021 Discovery Hearing and Case Management Conference.

1. **Status of ZHP's Court-Ordered Discovery**

The Court has ordered ZHP to produce a number of items of discovery by June 4, 2021 (after providing an extension at ZHP's request), and Plaintiffs look forward to assessing the production upon its receipt. (5/12/2021 Tr. 22:2-3).

2. **Plaintiffs' Fully Briefed Motion to Compel the Production of Baohua Chen's Custodial File**

This motion is ripe for the Court's decision.

3. Plaintiffs' Motion to Compel Documents Withheld as Purported Chinese State Secrets

This motion is also ripe for the Court's decision. Nevertheless, ZHP filed a meritless motion to strike Plaintiffs' reply brief or file a sur-reply on June 1, 2021. (ECF 1284). ZHP baselessly states that "Plaintiffs' reply brief raises, ***for the first time***, arguments with respect to *Societe Nationale Industrielle Aerospatiale v. United States Dist. Ct*., S.D. Iowa, 482 U.S. 522 (1987) and *Richmark Corp. v. Timber Falling Consultants*, 959 F.2d 1468 (9th Cir. 1992)." (ECF 1284, p. 1). In fact, Plaintiffs analyzed both decisions in their opening brief and explained that "the extremely limited extent to which any of the documents may bear on China's security or national interests, entirely from a non-substantive administrative perspective, is greatly outweighed by Plaintiffs' right to obtain the discovery ordered in this litigation." (ECF 1231-1, p. 15-17). The *Societe Nationale* and *Richmark* factors are non-exhaustive and meant to arrive at the type of balancing contained in Plaintiffs' original brief. *See Richmark*, 959 F.2d at 1474. Thus, Plaintiffs raised this argument in the second point in that brief: "**PLAINTIFFS' SIGNIFICANT INTEREST IN THE DOCUMENTS EXCEEDS THAT OF THE ATTENUATED STATE SECRET INTEREST**." (ECF 1231-1, p. 15). Moreover, ZHP argued each of the factors in their opposition to Plaintiffs' motion. (ZHP's Opp. Br. 8-24). Plaintiffs were certainly permitted to respond to those arguments in their reply brief. *See Bayer AG v. Schein Pharm., Inc.*, 129 F. Supp. 2d 705, 716 (D.N.J. 2001) (stating that "It is axiomatic that reply briefs should respond to the respondent's arguments…"). The Court should therefore deny ZHP's motion and, in accordance with Plaintiffs' reply, compel the production of the documents withheld as purported Chinese state secret documents.

4. Hetero's Ongoing Discovery Deficiencies

There continue to be deficiencies in Hetero's production, and Plaintiffs have repeatedly requested documents necessary for upcoming 30(b)(6) depositions including key items such as (1) chromatograms for (a) the NDMA testing that was done by Analys labs and (b) the in-house GC residual solvent testing that Hetero did during batch manufacturing; (2) the underlying data for the chromatograms from the GC and GC-MS machines, including but not limited to data from Empower; (3) the process development documents, including but not limited to any genotoxic analysis performed, with regard to the development of Hetero's Process III, which Hetero admitted created NDMA impurities in its API. As to Item 3, there appears to be no possibility that Process III was developed with no written documentation regarding how it was developed, the experimentation done to develop it, the theoretical analysis done to develop it, etc., yet Plaintiffs have still not received any of those documents. These categories of documents regarding process development have been repeatedly requested from Hetero for months now, and have been identified to the Court in numerous letters, but they continue not to be produced. Production of those documents is crucial as the 30(b)(6) deposition with regard to those issues, having been delayed multiple times due to this non-production, is currently set for June 8 and 9, 2021, and the failure to produce them is significantly prejudicing Plaintiffs' ability to prepare for that deposition.

Plaintiffs have also similarly previously requested all documentation regarding any genotoxic analysis done during the Process III development phase, and, again, have received no documents. On May 26, 2021, Dr. Kumar testified that the potential genotoxic impurity analysis performed by Hetero during the development of Valsartan Process III was done using a software called Derek. Plaintiffs have searched Hetero's production but have not found any evaluations

performed utilizing Derek for Valsartan pre-July 2018 other than specifically for DIPEA, just a single evaluation done post-development in 2019. These documents, again, are relevant to the 30(b)(6) topics to be covered on June 8 and 9, 2021, and the failure to produce them is significantly prejudicing Plaintiffs' ability to prepare for that deposition.

In addition, documents show that Hetero created NDMA, NDEA, and other nitrosamines in-house as reference standards. Testimony regarding the creation of these impurities pointed to handwritten lab notebooks. While Hetero produced pages from those notebooks, to date, Hetero has only produced the covers and TOC for the laboratory record book for a single impurity. The testimony stated that the lab notebooks were dated when initiated, which dates significantly predated Hetero's first claim to have been notified of the potential for nitrosamine impurities, yet there has been no documentation, such as the covers, TOC, etc. produced for any lab notebook evidencing such initiation date.

Plaintiffs have requested that if it is Hetero's position that it produced the documents, to identify them by bates number. Plaintiffs also requested that to the extent any of the above information exists but has not been produced, to advise what documents exist and when they will be produced. With regard to the Derek system, and any other systems that may have been used to conduct potential impurity analysis of Valsartan Processes I-III, Plaintiffs requested that Hetero provide (or the extent it believed it already produced, to identify by bates number) all results related to Valsartan Processes I-III, all SOPs or other procedures documenting the use of Derek and/or other such software, all communications regarding the results of any such analysis of Valsartan Processes I-III, details of the software(s) and versions used during the 2012-2019 time frame, and all software manuals and documentation regarding Derek and/or other such software. The fact

that software supposedly used by Hetero to test for genotoxic impurities during process development was never identified by Hetero to Plaintiffs as part of their list of relevant ESI until it happened to be mentioned by one of their witnesses during deposition is particularly troubling.

In addition, there are numerous specific documents and document categories that Plaintiffs have requested that are still not identified as produced, including ones that have been specifically listed on previous letters to this Court and/or otherwise identified to Hetero.

Plaintiffs have continued to communicate with Hetero and to request production or identification of the bates numbers if Hetero contends the documents have been produced. While this has occurred with regard some of the requested documents, numerous documents remain missing.

Requested Action by the Court

Plaintiffs have met and conferred with Hetero numerous times over the course of months, but to the best of Plaintiffs' ability to determine, the above identified deficiencies, as well as others identified in the various meet and confers, remain. Thus, for requested documents and categories of documents that have not been provided by Hetero, Plaintiffs request that the Court order that by June 7, 2021, Hetero produce all remaining requested documents and categories of documents, and to the extent that it does not, notify Plaintiffs that such documents do not exist and whether that non-existence is as a result of loss or destruction.

5. Aurobindo's Recent Discovery Abuses and Misrepresentations

A. Plaintiffs' Letter

Plaintiffs received the Court's e-mail on May 27, 2021, indicating that their letter (ECF No. 1272) was not received prior to the order on Plaintiffs' Motion to Strike and Suppress

Aurobindo's Defenses (ECF No. 1275) being sent for docketing. Plaintiffs will be prepared to discuss this letter at the status conference. Unfortunately, even though less than a week has passed since Plaintiffs sent their letter to the Court, Aurobindo has continued to withhold relevant documents from Plaintiffs until the eleventh hour. Plaintiffs reiterate that sanctions are warranted against Aurobindo, as their improper conduct has continued unabated even since the oral argument on Plaintiffs' motion.

B. Additional Last-Minute Document Dumps

Aurobindo's last 30(b)(6) designee, David Palew (an employee of one of the US entities), was deposed on Thursday, May 27, 2021. The night before his deposition, at 7:47 p.m., Aurobindo emailed Plaintiffs to let them know that Aurobindo still had 191,821 documents that it had yet to produce to Plaintiffs, "including documents for Blessy Johns [(Aurobindo's 30(b)(6) designee on regulatory issues who has already been deposed]) and David Palew among other custodians." Until May 27, 2021, the night before this deposition, Aurobindo had not disclosed to Plaintiffs or the Court that it still had not produced what appears to be a substantial volume of custodial data for its US witnesses and from noncustodial sources in both the US and India.

Based upon this last-minute disclosure, Aurobindo "propose[d] re-scheduling Mr. Palew's deposition." Once again, keeping in mind that Plaintiffs need to meet their expert deadlines, Plaintiffs informed Aurobindo that they intended on proceeding with the deposition.

The very next morning, thirty minutes before Mr. Palew's deposition (on the topics of sales to downstream customers) was scheduled to start, Aurobindo produced a spreadsheet, containing all sales of API to external (non-Aurobindo) entities. This data has been readily available to Aurobindo since the outset of this case.

Plaintiffs cannot fathom a world in which this behavior is appropriate or fair. Beyond that, these last-minute dumps have prevented Plaintiffs from examining witnesses on clearly relevant documents. There has not been a single Aurobindo deposition in this case yet where Aurobindo has not produced documents for a deponent immediately before (or even during) the deposition, as shown in the updated production log from Aurobindo. (Ex. A hereto). Plaintiffs have once again added in the deposition dates in yellow and highlighted the eleventh-hour productions made for the specific deponents just before (or during) each deposition.

C. Documents Yet to Be Produced

Aurobindo informed Plaintiffs last week that it does not anticipate completing its production of the remaining 191,821 documents until June 8, 2021, less than one month before Plaintiffs' expert reports are due. While Aurobindo has had years to familiarize itself with these documents, Aurobindo's belated productions have forced Plaintiffs to attempt to digest them in a matter of weeks. Needless to say, this places Plaintiffs in a difficult position.

During his deposition, Sanjay Singh also identified numerous sources of data that have yet to be produced, including but not limited to, the Agile system, flash drives, the W drive, Z drive, paper logbooks from the quality assurance department, other shared drives for various departments including the regulatory department, as shown in the attached transcript. (Ex. B hereto). Plaintiffs assume but have not received verification that all of these sources of data are being produced and will be fully produced by June 8, 2021.

Plaintiffs will likely need to reapproach Aurobindo at a later date regarding second depositions of defendants (or depositions of different deponents whose significance has now become clear in light of the newly produced documents). However, for the time being, Plaintiffs

now need to review the belatedly produced documents (and those documents with recently updated metadata) and will not be in a position to schedule second depositions of defendants until they have had time to complete that review.

In the meantime, Plaintiffs ask that the Court to require Aurobindo to serve a certification upon Plaintiffs on or before June 8, 2021, which states that their production is substantially complete.

6. Teva's Privilege Logs and Document Follow-Up

This is an update only. Teva's privileges logs collectively constitute the largest claims of privilege amongst all Manufacturer Defendants, numbering in the tens of thousands of purportedly privileged documents. Plaintiffs have meticulously gone through Teva's thousands of privilege assertions, and are attempting to meet and confer with Teva about them. To date, Teva has not made itself available to discuss this issue. Plaintiffs are hopeful Teva will engage on this matter without the need for Court intervention. Plaintiffs also are in communication with Teva about a number of different document issues arising out of recent Teva depositions; however, there is nothing ripe for the Court at this time.

7. Plaintiffs' Discovery to Retail Pharmacy and Wholesaler Defendants

After months of negotiation since Plaintiffs first served *draft* document requests on Retail Pharmacy and Wholesaler Defendants in December 2019, the Parties have largely reached agreement on final sets of discovery, which are attached hereto as Exhibits C and D, respectively. The remaining issues for the Court's consideration are outlined below.

A. Discovery to Wholesaler Defendants

The Parties have reached agreement on the requests attached as Exhibit D and ask the Court to enter them. The Parties will continue to confer about other potential document requests.

B. Discovery to Retail Pharmacy Defendants

Only a single draft request, Request No. 6, remains at issue. This request seeks the following:

> 6. For VCDs, documents reflecting your inventory forecasts, demand forecast, days on hand ("DOH") forecasts, or similar documents ordinarily transmitted to a supplier to show approximately how much inventory of VCDs you had on hand, or the quantity of VCDs expected to be ordered based on demand. [Plaintiffs are willing to discuss whether this can be limited to "sufficient to show" or exemplar documents only.]

(Ex. C hereto).

This narrowly tailored request seeks specific documents relevant to the issue of traceability. One potentially relevant issue in this litigation is whether a particular plaintiff received valsartan pills from specific lots. This is because Defendants may argue that some but not all valsartan was contaminated with nitrosamines. In this event, a plaintiff may need to show that a particular batch of valsartan API went into a particular lot of finished dose valsartan; and in turn, that the lot of finished dose valsartan dose made it into the hands of and was ingested by the plaintiff. The Parties and Magistrate Judge Schneider have generally referred to this as "traceability."

Manufacturer Defendants maintain detailed batch/lot information for all valsartan API and finished dose valsartan. This includes information showing the specific lots of finished dose valsartan Manufacturer Defendants sold downstream. Retail Pharmacy Defendants have long argued that they do not keep records of the lot number for finished dose valsartan dispensed to a

particular plaintiff. However, in recent depositions of Manufacturer Defendants, Plaintiffs have learned that various Retail Pharmacy Defendants provide inventory forecasts and estimates for finished dose valsartan. For example, a retailer tells a manufacturer that they only have 100 units of valsartan left; that based on demand they will deplete that inventory on hand in 3 weeks; and that they need to order another 100 units of valsartan. In tandem with Manufacturer Defendants' sales records (which will show, inter alia, the specific lot of valsartan sold and date of sale), Plaintiffs will be able to extrapolate which lots of finished dose valsartan were supplied to which Retail Pharmacy Defendants and when. Armed with knowing which specific lots a Retail Pharmacy Defendant had on hand, and knowing how quickly the retailer believed it would deplete that inventory, Plaintiffs can triangulate which specific lots would have been dispensed to which plaintiffs during which windows of time.

Retail Pharmacy Defendants oppose these requests on three bases (i) relevance, (ii) undue burden and proportionality, and (iii) beyond the scope of the Special Master's instructions on custodial discovery. All three of these assertions lack merit.

First, the documents sought are clearly relevant, let alone discoverable, for the reasons identified above.

Second, Retail Pharmacy Defendants have not articulated any undue burden with the requisite specificity. "When a party objects that a discovery request as irrelevant or unduly burdensome, that party must show specifically how the request is burdensome, oppressive, or irrelevant." *See, e.g.*, *Knaupf v. Unite Here Local 100*, Civ. A. No. 14-6915, 2015 WL 7451190, at *4 (D.N.J. Nov. 23, 2015) (internal quotations and citation omitted). Bald assertions of undue burden will not suffice. *Id.* Here, Retail Pharmacy Defendants have not articulated any burden,

let alone any that is "undue." They have not shared with Plaintiffs, for instance, what types of responsive documents that keep, where, for how far back in time, and what collection and production of the documents would entail. This falls well short of defendants' burden, as the party resisting discovery. *See id.*; *see also Costantino v. City of Atlantic City*, 152 F. Supp. 3d 311, 328 (D.N.J. 2015) (Schneider, M.J.) (overruling unsubstantiated objections on the basis of undue burden; "[i]t is unacceptable for a defendant to avoid legitimate discovery because it does not devote reasonable resources to defending a case."). As to proportionality, without any articulation of the burden, neither Plaintiffs nor the Court can properly assess Defendants' proportionality objection.

Third, Retail Pharmacy Defendants incorrectly claim this request seeks "custodial" discovery, which the Special Master already declined to order at a prior CMC in May. This request does not seek custodial discovery. In fact, the agreed-upon definitions/instructions specifically state that they do not require custodial searches of multiple employees' files. (*See* Ex. C hereto). Rather, this request is no different than the Parties' other agreed-upon requests that narrowly seek specific types of documents, e.g., representations/warranties, or supply agreements. Further, Plaintiffs explicitly expressed a willingness to limit request no. 6 to a "sufficient to show" request, or a request for exemplar documents. (*See* Ex. C hereto). But Retail Pharmacy Defendants rebuffed that offer.

Finally, to the extent Retail Pharmacy Defendants may argue that they have not had sufficient time to negotiate this request, Plaintiffs already agreed to address that concern. Last week, Plaintiffs agreed to remove this request from the current set of requests, and to continue to negotiate it with Retail Pharmacy Defendants. This is in fact what Plaintiffs and Wholesaler

Defendants agreed to do with substantially similar requests – continue to negotiate them while other requests are entered by the Court. Retailer Pharmacy Defendants initially signaled they would agree to do the same, but then changed tact on the eve of Memorial Day weekend and informed Plaintiffs that they would rather just argue this request now to Your Honor. Thus, any complaint about the timing of this request is of Retailer Pharmacy Defendants' own doing, given Plaintiffs' willingness to continue to negotiate this request.

8. Depositions of Third Party Payors

Plaintiffs reached out to the Defense Liaison Counsel and the defendants handling the plaintiff fact sheet submissions for Employers and Laborers Local 100 and 397 and Steamfitters Local 439 to confirm the completion of the fact sheets, production of documents, and to determine whether Defendants intended to take the depositions of these entities. Given the timing of the discussion, Plaintiffs offered that these depositions could be taken in the second phase of discovery. After conferring among themselves, Defendants have taken the position that CMO-23 does not contemplate conducting discovery on entities not currently named as putative class representatives and that CMO-23's deadlines do not impose any discovery obligations related to these TPP Plaintiffs, unless or until they are added as putative class representatives to an amended complaint.

Plaintiffs are reporting the status of this matter to the Court along with the ongoing discussions with Defendants and will seek guidance from the Court as to the timing to resolve these issues.

9. Bellwether Plaintiffs' Depositions Update

Plaintiffs can report that 7 of 10 Bellwether Plaintiffs selected to have their depositions taken prior to June 1 have been deposed. The other 3 Bellwether Plaintiffs depositions are going forward but needed to be scheduled after June 1 with two being scheduled after June 1 at the Defendants' request and the other being rescheduled due to the Plaintiff being diagnosed with COVID. Plaintiffs and Defendants continue to schedule deposition dates for the remaining 18 Bellwether Plaintiffs, and the Parties anticipate that all plaintiff depositions will be completed per the Court's scheduling order. All 28 Bellwether Plaintiffs remain in the pool, and at this time, Plaintiffs do not anticipate any cases will be dismissed.

10. Status of Treater Deposition Protocol

The Parties are continuing to negotiate the Treater Deposition Protocol and anticipate reaching agreement on the majority of issues. To the extent any issues remain unresolved, the Parties will present them to the Court for resolution. Notwithstanding the continuing negotiations, the Parties have agreed that they may begin scheduling the deposition of one prescribing physician and one treating physician for the first 10 Bellwether Plaintiffs.

11. Defendants' New Interrogatories and Requests for Production

On May 24, 2021, Manufacturer Defendants propounded what they styled "Defendants' First Set of Global Interrogatories and Requests for Production to Plaintiffs." (*See* Ex. E hereto). These new interrogatories and document requests appear to be directed at all plaintiffs, in all three master actions (personal injury, economic loss, and medical monitoring). Defendants' unilateral decision to propound this new written discovery at the end of Phase 1 of fact discovery would open

a whole new phase of discovery – the time for which has long passed – and should be stricken and denied. The surprise propounding of this new discovery is troubling for multiple reasons.

First, the operative scheduling order does not provide for Defendants' service of new written discovery, and no such discovery was requested by Defendants when the Defendants advised the Plaintiffs and the Court of all discovery that needed to be scheduled/rescheduled earlier this year when the deposition deadline was moved to June 1, 2021.

Second, contrary to the years-long practice in this litigation, Defendants made no effort to meet and confer with Plaintiffs about these new requests. As Your Honor is aware, Judge Schneider instituted a process at the outset of this litigation under which the Parties are to exchange draft/proposed discovery requests before formally serving them; then the Parties should meet and confer; and any lingering disputes are brought to the Court during a case management conference; and finally, the final set of requests is entered by the Court. Your Honor will recall this most recently in the context of Plaintiffs' negotiation of proposed document requests to Retail Pharmacy and Wholesalers Defendants. Plaintiffs served draft document requests on these defendants in December 2019, and were required to confer with those defendants for months before finalizing and formally serving the requests. Manufacturer Defendants' unilateral service of new interrogatories and documents, without any discussion with Plaintiffs or the Court beforehand, violates the norm in this case. Thus, the new interrogatories and requests should be stricken.

Third, and more to the point, interrogatories are disallowed in this litigation, which is yet another reason to strike these new discovery requests. Judge Schneider established very early in this litigation that Parties are not to serve interrogatories. In lieu of interrogatories, the Court ordered both sides to complete fact sheets. For example, in discussing the timeframe for *Plaintiffs*

to serve written discovery on Defendants, Magistrate Judge Schneider made clear there will not be any interrogatories in this case, which was the same practice he and Judge Kugler followed in the *Benicar* MDL:

> MR. PAREKH [for plaintiffs]: We need to get a handle on the volume of documents that's going to be produced in core discovery and until we -- we're going to get a large number of them actually this Friday, I believe, and then once we see the volume and the type of documents and what's in there, we'll have a better idea. But I think targeting the end of August for a meeting would make the most sense to give us enough time to actually absorb what's in those documents.
>
> MR. GOLDBERG [for defendants]: Your Honor, it seems like we're missing a step. I mean, I think we would expect there to be document requests served, Interrogatories served, based on –
>
> THE COURT [Magistrate Judge Schneider]: **No Interrogatories. We do the fact sheets.**
>
> MR. GOLDBERG [for defendants]: Okay, that's fine. But document requests served so that we can then have these discussions in the context of those requests

(6/26/2019 Tr. at 16-17 (emphasis added)).

Consistent with this early ruling, none of the parties have served any interrogatories in this case in the last three years – until Manufacturer Defendants' un-negotiated new interrogatories of May 24, 2021. For this reason alone, Manufacturer Defendants' new interrogatories are improper. Alternatively, if the Court were to consider a change in practice to allow interrogatories, then the Parties would need to meet and confer about a schedule for the timing, exchange, and answering of interrogatories and new document requests propounded by both sides, and the substance thereof. This process would clearly inject a new unanticipated distraction into the case just as the Plaintiffs are focused on finishing manufacturer depositions, continuing to police inadequate productions,

and the critical work to get the Plaintiffs' expert reports done. In this context, Plaintiffs have a number of material questions they would have asked Defendants via interrogatories in this matter, but have not done so because of Judge Schneider's directive and the scheduling order not allowing it. If this is no longer the case, then Plaintiffs should have just as much an opportunity to propound interrogatories as Manufacturer Defendants. At the end of the day, the litigation has moved beyond interrogatories, and they should not be permitted at this juncture.

Fourth, without getting too much into the merits of Manufacturer Defendants' new interrogatories and requests, they suffer from a number of facial infirmities. The interrogatories are contention-style and largely aimed at unearthing Plaintiffs' case theories, expert opinions and the bases thereof, and facts mustered for same by Plaintiffs' attorneys, not Plaintiffs themselves. Most if not all of the information sought will be disclosed under the scheduling order at the appropriate time, e.g., along with expert reports. To require Plaintiffs to answer these premature questions now will be prejudicial to them, as it would require Plaintiffs to divert resources from taking the remaining depositions scheduled (all of which should have been completed by June 1, but will not be because of Manufacturer Defendants' requests for later dates or failure to timely produce documents), and to meet the court-ordered deadlines for expert reports, as well as the briefing on the motion to amend, and multiple other issues that are playing out already. Additionally, many of the new document requests to Plaintiffs are duplicative of the lengthy, heavily negotiated, court-ordered Plaintiff Fact Sheets, and to the extent they are not that is because they are improper, unduly prejudicial contention, and constitute expert witness discovery. Other substantive issues exist with Defendants' new interrogatories and requests, but because they were not negotiated beforehand, Plaintiffs will reserve their other substantive objections until the

appropriate time directed by the Court, if the requests are not stricken, which is Plaintiffs' primary request.

For these reasons, Plaintiffs ask the Court to strike the Manufacturer Defendants' new interrogatories and document requests.

12. Teva Clawback Request

Teva has attempted to clawback a number of purportedly privileged documents over the last few months. The frequency of Teva's clawback requests calls into question the adequacy of its privilege screening process. Nevertheless, Plaintiffs have overwhelming agreed to nearly all of Teva's clawback requests to date, save for three documents (two of which are near-identical copies of the same email string) because Teva proposes overly broad redactions of non-privileged information from them. Plaintiffs do not say more here due to Teva's confidentiality designations for these documents, but will be prepared to argue the documents at the CMC or in camera at another time set by Your Honor.

13. Plaintiffs' Request for De-Designation of Confidential Documents

In accordance with the Court's two Orders addressing the overbroad confidentiality designations on the part of Torrent and ZHP, Plaintiffs reached out to all of the Manufacturer Defendants and requested that they all affirmatively de-designate improperly designated documents in accordance with the Orders. It was Plaintiffs' understanding that these Orders were intended to serve as roadmaps to guide not only ZHP and Torrent, but also the other manufacturers, to bring the productions into compliance with the Orders. (ECF 1269, p. 9 n.6, 15 n.10 (holding: "It is hoped that this detailed approach will provide the parties guidance on future designations of confidentiality and challenges under the Protective Order," and "It is hoped that the parties will

follow this determination with respect to other documents for which the FDA has made FOIA determinations and, to the extent that the FDA has found that the documents are subject to production on a FOIA request, de-designate the documents as confidential."); *In re Valsartan N-Nitrosodimethylamine (NDMA), Losartan, and Irbesartan Prods. Liab. Litig.*, --- F. Supp. 3d ----, 2021 WL 75258, at *8 (D.N.J. Jan. 8, 2021) (ECF 717, p. 20). The obvious benefit for the Court and the Parties is to avoid the need for lengthy repetitious challenges that strain resources and waste time when it is obvious in most cases that the Orders require de-designation. The same holds true for Defendants' massively overbroad designations of deposition and deposition testimony as confidential, and Plaintiffs asked Defendants to remedy that as well.

Defendants of course prefer the path of most resistance, demanding that Plaintiffs challenge every document and designation one by one. This makes no sense in light of the record the Court has worked so hard to create. Therefore, Plaintiffs ask that the Court direct the manufacturers to de-designate their confidentiality designations per the Court's Orders, and serve replacement documents with no stamp in accordance with the ESI protocol so that they are carefully delineated, within thirty days. Defendants have been on notice of this issue since the entry of Judge Schneider's Order on January 8, 2021, so they cannot reasonably complain about this proposed deadline. To the extent the Defendants fail to affirmatively take advantage of this opportunity and fix the over-designations, and Plaintiffs must file applications with the Court, Plaintiffs request that the Order provide that sanctions will be assessed for remaining designations that the Court must ultimately take the time to review and strike.

14. Global Phase I Discovery Update

The operative scheduling order (ECF 863) provides that June 1, 2021 is the "[d]eadline to complete first phase of fact discovery," which includes all depositions of Manufacturer Defendants; all depositions of current economic loss and medical monitoring putative class representatives; and depositions of ten of the current personal injury bellwether plaintiffs. To date, all Manufacturer Defendants have at least one or more witness(es) who have yet to be deposed. The reasons for this vary – from the benign (e.g., COVID travel restrictions complicating a German witness's travel to a neighboring country because local law disallows extra-jurisdictional depositions) to the more fault-worthy (e.g., Hetero's and Aurobindo's repeatedly tardy document dumps and attendant re-scheduling requests). Regardless, Plaintiffs do not believe there is any need to modify the scheduling order at this time. Plaintiffs are committed to adhering to the current schedule, including the July 6, 2021 deadline for service of general causation expert reports, notwithstanding the many defense witness depositions remaining. If a particular deposition poses an acute scheduling issue, Plaintiffs will approach the Court at the next CMC.

Plaintiffs have identified a number of production deficiencies in the course of deposing Manufacturer Defendants' witnesses to date. Plaintiffs have a variety of pending requests to each Manufacturer Defendant about these deficiencies, and some have been ruled on by the Court. More are expected based on recent depositions. Plaintiffs expect the Parties will continue working to resolve these deficiencies, with any impasses being brought to the Court's attention.

Plaintiffs believe Defendants have now deposed all but two putative class representatives, and the depositions of personal injury plaintiffs remain ongoing by agreement of both sides, with a deadline at present of October 4, 2021.

15. Plaintiff Fact Sheet Show-Cause Submission

Plaintiffs will be prepared to discuss any remaining orders to show cause at the case management conference.

Respectfully,

ADAM M. SLATER